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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,049	03/02/2002	Chi Yung Fu		3263

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Chi Yung Fu
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San Francisco, CA 94131

EXAMINER

LY, CHEYNE D

ART UNIT PAPER NUMBER

1631

DATE MAILED: 10/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/087,049	FU, CHI YUNG	
	Examiner	Art Unit	
	Cheyne D Ly	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 9 and 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-27 and 30 is/are rejected.
- 7) ☒ Claim(s) 28 is/are objected to.
- 8) ☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election of Group I, claims 1-28, and 30, living humans, staphylococcus aureus, diabetes, and acetone, filed August 21, 2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claim 9 has been withdrawn due to the claimed subject matter being directed to subject matter other than the elected species.
3. Claims 1-8, 10-28, and 30, living humans, staphylococcus aureus, diabetes, and acetone are examined on the merits.

OBJECTIONS

4. The abstract of the disclosure is objected to because the instant abstract has more than 150 words. Correction is required. It is suggested that a new abstract is submitted on a separate sheet of paper. See MPEP § 608.01(b).
5. The title of the invention is not descriptive because the instant title is directed to system while the instant claims are directed to a method. A new title is required that is clearly indicative of the invention to which the claims are directed.
6. Claim 28 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

CLAIM REJECTIONS - 35 U.S.C. § 112, SECOND PARAGRAPH

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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8. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Specific to lines 1 and 2, the term “supermarkers” causes the claim to be vague and indefinite because it is unclear what criteria are being used to determine that a particular marker is a “supermarker” (marker indicative of a “super” condition or a very big marker). Clarification of the metes and bounds to the instant claim is required.

CLAIM REJECTIONS - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1-8, 10-27, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips (US 6,221,026 B1) taken with Gardner et al. (1996) in combination with Matteucci et al. (2000), Kanety et al. (1994), and Brook et al. (1995).

12. Phillips discloses an improved analytical method for detecting volatile organic compounds in the breath of 50 normal humans as directed to various diseases (Abstract etc., column 6, lines 59-61) such as expired air acetone from glucose metabolism in diabetes mellitus (column 12, lines 51-55). Volatile markers are ranked and selected according to Tables 1-2. Breath analysis is a form of non-invasive means of detecting said volatile markers (column 1, lines 41-43). Data of said analytical method is processed with an algorithm (column 11, lines 18-26), as in instant claims 1, 6-8, 10, 11, and 21

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13. Gradient curves were analyzed by logistic regression to eliminate false positives and false negative results (column 15, lines 28-34), as in instant claims 2 and 14.

14. Phillips discloses an apparatus for the detection of volatile markers (artificial olfactory system) comprising a microprocessor-controlled device and a heated breath reservoir (heat source, microwave) (column 10, lines 40-67 to column 11, lines 17), as in instant claims 3, 23, 26, and 27.

15. Data analysis comprises chemical identity, area under a curve, and quality fit (column 11, lines 19-25), as exemplified by Figure 10 for 2-methyl alkanes as in instant claim 15.

16. Cell membrane fatty acids are degraded to alkanes by lipid peroxidation (column 7, lines 31-39), as in instant claims 16 and 17.

17. Further, Phillips discloses oxygen free radical activity increases in ischemic heart disease (column 4, lines 37-39), as in instant claims 22.

18. However, Phillips does not disclose the use of artificial neural network.

19. Gardner et al. discloses a method of analyzing and filtering data from diabetic patients using artificial neural networks wherein a training set was used (Abstract etc.), as in instant claims 4, 5, 12, 13, and 24.

20. Further, the artificial neural networks of Gardner et al. comprises three layers: an input layer, output layer, and hidden layer which consists of a number of nodes connected to the input and output nodes by mathematical algorithms (weight) (page 943, column 1, Appendix, The Artificial Neural Network §), as in instant claim 25.

21. However, Phillips and Gardner et al. do not disclose the limitation of markers is used to predict glucose change and erythrocyte cells.

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22. Matteucci et al. discloses use of biological markers as major predictors of type 1 diabetes wherein blood glucose is measured and diabetic patients wherein diabetic patients had higher level of blood glucose than control subjects (Abstract etc.), as in instant claims 18 and 19.

23. However, Phillips, Gardner et al. and Matteucci et al. do not disclose the limitation of markers are used to detect an overeating condition.

24. Kanety et al. discloses a method of using markers such as insulin receptors for diagnosing the effects of overeating as directed to diabetes mellitus, as in instant claim 20.

25. However, Phillips, Gardner et al. Matteucci et al., and Kanety et al. do not disclose the limitation of staphylococcus aureus.

26. Brook et al. discloses a diagnostic method for bacteriology, staphylococcus aureus, with patients with a predisposition of diabetes mellitus (Abstract etc. and page 2384, column 2, lines 16-23), as in claim 30.

27. An artisan of ordinary skill in the art at the time of the instant invention would have been motivated by the improvement disclosed by Phillips to use the analytical method for detecting volatile organic compounds as directed to the treatment of diabetes mellitus with artificial neural network as taught by Gardner et al., markers are used to predict glucose change and erythrocyte cells as taught by Matteucci et al., using markers for diagnosing the effects of overeating as directed to diabetes mellitus, and diagnostic method for bacteriology, staphylococcus aureus, with patients with a predisposition of diabetes mellitus as taught by Brook et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to use method for detecting volatile organic compounds as taught by Phillips, Gardner et al. Matteucci et al., Kanety et al., and Brook et al.

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CONCLUSION

28. NO CLAIM IS ALLOWED.

29. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

30. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

31. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

32. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly
10/16/03

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER